K121636

OCT 24 2012

2. 510(k) SUMMARY

Sponsor Name: TGM Medical, Inc.
5145 Golden Foothill Parkway, Suite 175
El Dorado Hills, CA 95762

510(k) Contact: Prakash Pai
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Date Prepared: Revised October 23, 2012 to support Supplement 1 and 2 based on FDA AI requests for K121636 (August 15th, 2012 and September 26, 2012)

Trade Name: ZENITH Hip System

Common Name: Hip prosthesis; porous coated and nonporous coated

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358, Class II device, Product Code LPH).

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353, Class II device, Product Code LZO).

Device Description:
The ZENITH Hip System (ZHS) offers a proximally porous and nonporous femoral stem component each compatible with all femoral heads, acetabular components, and cancellous bone screws of the Helicon Hip System (HHS). The porous ZHS stems are manufactured from forged Titanium (Ti) alloy, and employ a porous-coating made from commercially pure Ti (CPTi) beads. The nonporous ZHS stems are manufactured from forged cobalt chrome (CoCr) alloy. The porous Ti stem is a straight, collarless design available in 6 sizes ranging from 10 to 15mm. The nonporous CoCr stem is a straight, collared design available in 8 sizes ranging from 8 to 15mm. Both stems feature a neck-shaft angle of 128°, a 12/14 Morse taper trunnion, neck relief, and a cylindrical fluted shaft. A distal centralizer manufactured from polymethylmethacrylate (PMMA) is available for cemented applications of the CoCr stem.

The ZHS also includes 36mm femoral heads and acetabular cups. The heads are manufactured from forged or wrought CoCr alloy. The 36mm inserts are manufactured from conventional UHMWPE. The heads are highly polished and are available in four neck offsets (-5mm, Neutral, +5mm, +10mm). The heads incorporate an identical female 12/14 Morse taper used on all predicate HHS CoCr heads. The 36mm inserts are compatible with predicate HHS acetabular shells ranging in size from 56 to 68mm. Refer to the compatibility table (new

Attachment 1 of the September 12, 2012 AI response/Supplement 1). The 36mm inserts are offered in neutral or 10 degree hooded configurations. Hooded inserts include an X-ray marker manufactured from wrought Ti alloy. The 36mm heads and mating inserts are also compatible with the Helicon Hip System.

Indications for Use:

The ZENITH Hip System is designed for total hip arthroplasty and is intended to be used with compatible components (femoral heads and acetabular cups) of the Helicon Hip System.

The indications for use are:

A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
C. Proximal femoral fractures.
D. Avascular necrosis of the femoral head.
E. Non-union of proximal femoral neck fractures.
F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The un-coated stem in the ZENITH Hip System is indicated for cemented use while the porous coated stem is indicated for non-cemented use.

Substantial Equivalence:

Technological Characteristics/Substantial Equivalence:

Consensus Orthopedics, Inc. (COI) licensed two of their Consensus Hip System (CHS) femoral stem designs along with their CHS distal centralizer to TGM Medical for use as the ZHS femoral components. These CHS stem designs were modified from the predicate CHS stem components cleared under K935193 and K922561 to incorporate neck reliefs. The distal centralizer is identical to that cleared under K922561. All ZHS implant components are compatible with all HHS femoral heads, acetabular components, and cancellous bone screws cleared under K111472 (Consensus had licensed their TaperSet Hip to TGM for the HHS).

COI licensed the predicate CHS 36mm CoCr femoral head design cleared under K070061 and a mating 36mm UHMWPE insert design to TGM Medical for use as part of the ZHS. The ZHS 36mm heads are identical in material and geometry as the CHS 36mm CoCr heads cleared under K070061. The mating ZHS 36mm inserts are identical in geometry as the CHS 36mm inserts cleared under K070061. The ZHS 36mm inserts employ identical material and outer dome/locking mechanism geometry as the predicate HHS 32mm inserts. The ZHS 36mm head/insert components are compatible with all ZHS and HHS implant components of the appropriate size.

Because the subject ZHS stems and 36mm head/insert components employ the same material composition and strength requirements, have the same or similar technological

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characteristics, and have similar indications as their predicate devices, the ZHS stems and 36mm head/insert components are substantially equivalent to legally marketed predicates (Table 2.1).

Table 2.1: Legally marketed predicates to which substantial equivalence is claimed.

510(k) Number	Trade Name	510(k) holder	510(k) Clearance
K922561	Consensus Total Hip System	U.S. Medical Products, Inc.	07/21/1993*
K935193	Consensus Hip System – Porous Coated Titanium Femoral Stem	U.S. Medical Products, Inc.	08/18/1994*
K032396	RingLoc 36mm Liners and Modular Femoral Heads	Biomet, Inc.	08/21/2003
K070061	36mm CoCr Femoral Head and 36mm [crosslinked] Acetabular Insert	Hayes Medical, Inc.	01/31/2007**
K060918	Excia Total Hip	Aesculap, Inc.	05/26/2006
K111472	Helicon Hip System	TGM Medical, Inc.	09/06/2011

Notes: *Cleared prior to the purchase of U.S. Medical Products by Hayes Medical in 1996. **Cleared prior to the change in company name from Hayes Medical to Consensus Orthopedics in 2008.

Non-Clinical Performance Data:
COI provided rights to reference their 510(k)s and supporting performance testing. The ZHS components were evaluated using a Failure Modes and Effects Analysis (FMEA). Non-clinical bench testing was carried out when geometry and/or material presented a new worst-case in comparison to predicate devices.

Bench testing included distal and proximal fatigue testing of the worst-case stem/head configurations, Range of Motion analysis, porous coating bond strength, and testing of the modular connection including pull-out and fretting corrosion. All of the observed results for the porous Ti and nonporous CoCr stem designs licensed to TGM medical demonstrate that the ZHS is as safe, as effective, and performs at least as safely and effectively as legally marketed predicates.

The 36mm head/insert components are proven through the use of predicate devices using the same head size, design, and material (K070061), the same mating insert size and design (K070061), and the same mating insert material composition (K032396). Therefore, no additional testing was deemed necessary over that used in support of the predicates based on identical design and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TGM Medical, Incorporated
% Mr. Prakash Pai
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OCT 2 4 2012

Re: K121636
Trade/Device Name: ZENITH Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO
Dated: October 16, 2012
Received: October 18, 2012

Dear Mr. Pai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121636

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: ZENITH Hip System

Indications for Use:

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The indications for use are:

A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
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Prescription Use __X__ AND/OR Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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